UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

BLUE CROSS BLUE SHIELD ASSOCIATION, et al., Plaintiffs, v. GLAXOSMITHKLINE LLC, Defendant.	CIVIL ACTION No. 2:13-cv-4663-JS

DEFENDANT'S MEMORANDUM OF LAW CONCERNING THE EFFECT OF *IN RE AVANDIA* ON DEFENDANT'S PENDING MOTION TO DISMISS THE COMPLAINT

Defendant GlaxoSmithKline LLC ("GSK") respectfully submits this memorandum of law concerning the effect of *In re Avandia Mktg., Sales Practices & Product Liab. Litig.*, 804 F.3d 633 (3d Cir. 2015) ("*In re Avandia*") on its pending motion to dismiss plaintiffs' complaint for failure to state a claim.

PRELIMINARY STATEMENT

GSK's motion to dismiss the complaint raises two distinct issues: (1) have the plaintiff insurers adequately pled "economic injury" under the federal RICO statute and state law?, and (2) are plaintiffs' claims barred by the applicable statutes of limitations because plaintiffs had inquiry notice that cGMP issues at the Cidra manufacturing facility possibly caused their alleged injuries? This matter was placed in the civil suspense file because the parties and the Court anticipated that the Third Circuit's decision in *In re Avandia* might provide added guidance as to whether plaintiffs have adequately pled RICO injury. *See* Dkt. No. 88. The decision has no bearing on the statute of limitations issue.

The Court in *In re Avandia* held that the plaintiff insurers adequately alleged a RICO injury by pleading that they overpaid for Avandia. Plaintiffs claimed that GSK's alleged fraud inflated the price of Avandia (a "price effect") or caused physicians to prescribe the drug more often in comparison to less expensive alternative therapies (a "quantity effect"). The Court accepted as true plaintiffs' allegation that these price and quantity effects were a direct result of the alleged misstatements about the drug's safety.

The type of injury alleged by the plaintiff insurers in this case is very different, and *In re Avandia* does not address it. The plaintiffs here accuse GSK of failing to fully inform them about the cGMP problems at the manufacturing facility in Cidra, Puerto Rico. Plaintiffs do not allege that these cGMP problems resulted in higher prices for the drugs manufactured at Cidra (a price effect), or that they caused an increase in the quantity of Cidra drugs prescribed by

physicians (a quantify effect). Rather, plaintiffs allege that the cGMP problems rendered the drugs "legally adulterated" under FDA's regulations, which, in turn, made the drugs "worthless." Plaintiffs allege that if they had known the drugs were "adulterated" due to cGMP issues at the plant, they would have removed the drugs from their formularies. In that event, Cidra drugs would not have been covered under the insurers' policies, and their patient plan members would have been forced to forego treatment with Cidra drugs or pay for the drugs on their own. Nothing in *In re Avandia* supports this theory of economic harm.

ARGUMENT

The type of injury alleged in *In re Avandia* is materially different than the type of injury alleged in this case. The difference supports GSK's argument that plaintiffs' injury allegations are deficient.

A. The Injury Alleged in *In re Avandia*

Avandia, Avandamet, and Avandaryl (collectively "Avandia") are used to treat Type 2 diabetes. The plaintiffs in *In re Avandia* alleged that clinical studies proved that patients taking Avandia experienced more heart attacks than patients taking competing diabetes medicines that cost less than Avandia. According to plaintiffs, GSK "deliberately concealed" this risk and "continued to promote Avandia as a safer treatment for diabetes despite the known risks of heart attack and disease." *In re Avandia*, 804 F.3d at 636. Plaintiffs alleged that, because GSK misrepresented Avandia's safety profile, the company was able to charge a significantly higher price for Avandia than the price charged by manufacturers of competing therapies. *Id.* Plaintiffs also alleged that misrepresentations concerning Avandia's safety profile caused physicians to

prescribe Avandia more frequently than they would have if they had known that Avandia caused more heart attacks than other diabetes medicines. *Id.*[1]

GSK moved to dismiss the complaint, in part on the grounds that plaintiffs had not adequately alleged economic injury. *Id.*, 804 F.3d at 637. GSK argued that the plaintiff insurers were not harmed because their injury was "predicated on the possibility of future events that might occur—namely, that the drugs purchased by the [insurers] will prove to be unsafe or ineffective" in actual use. *Id.*, 804 F.3d at 639.

The Court of Appeals rejected this argument, finding that the economic injury alleged by the insurers—paying an inflated price—was "not contingent on future events" because the injury did "not depend on the effectiveness of the Avandia that [the insurers] purchased, but rather on the inflationary effect that GSK's allegedly fraudulent behavior had on the price of Avandia." *Id.*, 804 F.3d at 640. The Court explained that the insurers' injury occurred when they paid the higher price, regardless of whether patients were injured when they took Avandia. *Id.* The supposed "effect on the price of Avandia," therefore, was "not contingent on future events." *Id.*

B. The Injury Alleged in this Case

Plaintiffs allege that between 1997 and 2006, they paid for 17 "At-Issue" drugs that were manufactured at Cidra. They say that Cidra was beset by numerous cGMP violations. Because of these violations, the drugs manufactured at Cidra were "adulterated" as that term is used in

[1] GSK denies that it misrepresented Avandia's safety profile, and the FDA has concluded, based on more recent data, that Avandia does ***not*** cause an increased risk of heart attack compared to competing diabetes medicines. *See FDA Drug Safety Communication: FDA requires removal of some prescribing and dispensing restrictions for rosiglitazone-containing diabetes medicines* (2013) ("The U.S. Food and Drug Administration (FDA) has determined that recent data for rosiglitazone-containing drugs, such as Avandia, Avandamet, Avandaryl, and generics, ***do not show an increased risk of heart attack compared to the standard type 2 diabetes medicines*** metformin and sulfonylurea."), available at http://www.fda.gov/Drugs/DrugSafety/ucm376389.htm (emphasis added).

FDA's regulations. Compl. [Dkt. No. 1-1] ¶ 2. Plaintiffs claim that an "adulterated" drug is *ipso facto* "worthless," *i.e.*, it has no value whatsoever. *Id.* ¶¶ 7-9. According to plaintiffs, if they had known the drugs were "adulterated," they "would have removed the drugs from their approved formularies and would not have paid for them." *See* "Plaintiffs' Brief in Opposition to Defendant's Motion to Dismiss the Complaint" ("Pl's Br.") [Dkt. No. 40] at 5.

C. *In re Avandia* Does Not Support Plaintiffs' Theory of Injury in this Case

Plaintiffs' theory of injury is premised on the assertion that drugs that are manufactured under conditions that do not comply with cGMP are "worthless." This premise is wrong as a matter of law. As GSK explained in its initial motion papers (*see* Dkt. No. 38-2 at 2), the FDA has repeatedly stressed that there may be nothing wrong with drugs manufactured under conditions that do not comply with cGMP. A drug manufactured under such conditions "may still meet its labeled specification, and the risk that the drug is unsafe and ineffective could be minimal."[2] Thus, the mere fact that a drug is "adulterated"—as that term is used by FDA—says nothing about whether the drug is safe, effective, or suitable for human consumption. If there was nothing wrong with the drugs manufactured at Cidra, then the drugs were not "worthless," and paying for the drugs cannot have caused plaintiffs economic harm. *See In re Digitek Prods. Liab. Litig.*, 821 F. Supp. 2d 822, 828 (S.D.W. Va. 2011) (private payors not injured by cGMP violations because a cGMP violation "does not mean there is necessarily something wrong with the drug."); *see also In re McNeil Consumer Healthcare Mktg. & Sales Practices Litig.*, 877 F. Supp. 2d 254, 271-72 (E.D. Pa. 2012) (consumers who purchased "adulterated" drugs failed to allege injury-in-fact because they did not allege that the drugs were "actually defective as to

[2] *See* FDA, *Facts About the Current Good Manufacturing Practices (CGMPs)* (2015), available at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ucm169105.htm.

them"); *Polk v. KV Pharm. Co.*, No. 09-588, 2011 WL 6257466, at *7-*8 (E.D. Mo. Dec. 15, 2011) (consumer not economically harmed by the purchase of an "adulterated" medicine because he did not allege that the medicine was unsafe or ineffective as to him); *Myers-Armstrong v. Actavis Totowa, LLC*, No. 08-4741, 2009 WL 1082026, at *4 (N.D. Cal. Apr. 22, 2009) (under California law, consumer who claimed he would not have purchased a medicine if he had known that it came from a plant that was not cGMP compliant was not injured because "adulteration due to lack of compliance with GMP requirements is not enough, without more, to state a claim"), *aff'd*, 382 F. App'x 545 (9th Cir. 2010).

The disconnect between the alleged failure to disclose the cGMP violations at Cidra and the quality of the drugs manufactured at Cidra undermines plaintiffs' claim of injury and distinguishes this case from *In re Avandia*. The price and quantity effects attributable to the alleged fraud in *In re Avandia* stemmed directly from the allegedly false statements about Avandia's safety. These statements made it appear that Avandia was safer to use than it actually was. According to plaintiffs, this false portrayal allowed GSK to charge a higher price for Avandia and increased Avandia's acceptance among physicians. The Third Circuit found that because these price and quantity effects were the direct result of the alleged false statements, they did not depend on patient harm and were not contingent on future events.

Unlike the plaintiffs in *In re Avandia*, the plaintiffs here do not allege that GSK made false statements about the features and benefits of any "At-Issue" drug. They allege instead that GSK failed to disclose the presence of cGMP violations at the site where the drugs were manufactured. Plaintiffs do not claim that this non-disclosure led to higher prices or to an increased number of prescriptions. Nor, in the vast majority of cases, do they allege that the

drugs manufactured at Cidra were actually defective.[3] Thus, unlike in *In re Avandia*, where the alleged fraudulent statements about Avandia's safety led directly to the alleged price and quantity effects, GSK's alleged non-disclosure concerning the cGMP issues at Cidra has no direct bearing on the quality of the "At-Issue" drugs, which are not alleged to be unsafe, ineffective, or otherwise defective (*i.e.*, did not meet their labeled specifications).

In order to adequately plead injury in this case, plaintiffs must do more than allege that drugs manufactured at Cidra were "adulterated" because of cGMP violations at the plant. They must also allege, at a minimum, (1) that the "adulterated" drugs were actually unsafe, ineffective, or otherwise defective, (2) that actually defective drugs were released to the market, and (3) that plaintiffs paid for drugs that were actually defective. It is not enough to allege, as plaintiffs do here, that the cGMP issues at Cidra ***might*** have rendered the "At-Issue" drugs defective or undermined GSK's alleged ***assurances*** that the drugs met their labeled specifications. *See* Pl's Br. at 5. To be sure, the Third Circuit stated in *In re Avandia* that insurers may adequately plead economic harm even if the alleged fraud does not cause physical harm ***to patients***. But they must still allege that the fraud caused economic harm ***to themselves***. In this case, plaintiffs' injury allegations fall short because an "adulterated" drug which is not actually defective, released to the public, and paid for by the insurer cannot be the cause of any economic harm.

The difference between drugs that are "adulterated" in the regulatory sense and drugs that are actually defective is well-recognized in FDA regulations and case law. Plaintiffs' unprecedented attempt to breach that wall would, if allowed, lead to a rush of new RICO

[3] As discussed in GSK's initial memorandum, a handful of the cGMP issues alleged in the Complaint do relate to the quality of finished drug products from particular manufacturing Lots of some "At-Issue" drugs. *See* Dkt. No. 38-2 at 4-9. These allegations are not sufficient to plead injury because Plaintiffs do not claim they paid for drugs from any of the affected Lots and, in most cases, the drugs from the affected Lots were not released to the market. *Id.*

litigation and, in effect, create a private right of action for enforcement matters that are exclusively reserved to the FDA. As plaintiffs admit, warning letters from the FDA are "frequent and routine," amounting to hundreds of letters each year. *See* Pl's Br. at 18. The Food, Drug and Cosmetic Act prohibits private enforcement for regulatory violations. *See* 21 U.S.C. § 337(a); *see also Buckman Co. v. Pls.' Legal Comm.*, 531 U.S. 341 (2001) (violation of FDA regulations not actionable under state law). If this court allows plaintiffs to proceed on the theory that "adulterated" drugs are "worthless," even if the drugs are not actually defective, there will be no end to RICO cases seeking treble damages for alleged cGMP violations, even when, as here, those violations do not implicate public health or safety. It is one thing to permit insurers to sue for economic harm when a drug manufacturer charges an inflated price based on false statements concerning a drug's safety. It is quite another to permit insurers to seek treble damages for drugs that are "adulterated" in the regulatory sense but are not alleged to be defective or dangerous. Nothing in *In re Avandia* supports such a result.

CONCLUSION

In re Avandia does not support plaintiffs' theory of injury in this case. GSK's motion to dismiss should be granted.

Dated: January 26, 2016

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that, on this 26th day of January, 2016, I caused to be served via e-mail and/or U.S. Mail a true and correct copy of **DEFENDANT'S MEMORANDUM OF LAW CONCERNING THE EFFECT OF *IN RE AVANDIA* ON DEFENDANT'S PENDING MOTION TO DISMISS THE COMPLAINT** on the following counsel:

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